

“Compounding Inferno – ‘For Office Use’”

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Who has experienced acute pain?

Who has experienced chronic pain?

Acute Pain

- Serves a physiologic purpose and it resolves with healing.

Not something anyone wants to put off!

- Prince V. Pain Management. *Drug Topics* April 2009

Chronic Pain

- Has no physiologic value and it may persist despite healing of injured tissue.
 - Can lead to permanent negative changes (“neural plasticity”) in the nervous system.
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- Prince V. Pain Management. *Drug Topics* April 2009

Reasons for Pain

Psoriasis

Sports Injury

Vascular Disorders

Lymphatic Disorders

Surgical

Work Accident

Fibromyalgia

Ulcers

Impending Death

Cancer

Auto Accident

Childbirth

Bone and Joint Disorders

FDA recognized in the
Food and Drug Modernization
Act of 1997 (FDAMA)
the importance of the practice
of compounding for
office use and that it should
not be banned.

Pain Treatments

- **Pharmacologic:** Skeletal muscle relaxants, acetaminophen, NSAIDs, narcotics, sucrose water (infants), anti-epileptics, anti-diarrheal, and anti-depressants
- **Non-Pharmacologic:** cold and hot; physical, aroma, occupational, musical and recreational therapy; meditation, and yoga

Issues with Narcotic Treatments

Street Value
Drowsiness
Constipation
Diversion
Disposal
Addiction

Delivery Devices not Tamper Proof or Resistant

Patient's Inability to Maintain Employment

Devices That Can Only Be Filled or Refilled in a Physician's "Office"

Why Is Compounding “For Office Use” Invaluable?

Provides a medicinal preparation that a prescriber can administer directly to a patient, in his or her “office” for immediate treatment of a problem.

“Other Office Use Compounds”

Dental Gum Inserts

Facial Peels

Numbing for Laceration Suturing

Bone Cements

Prostate Cancer Implants

Ophthalmic Injections, Topicals and Inserts

Ear Insufflations

Numbing for Intravenous Access

Radiological Testing

“In The Office” and “Similar Settings”

- Where’s the office?
 - Emergency Room
 - Football Field
 - Patient’s Home
 - Soccer Field
 - Hospital In-patient’s Unit
 - Baseball Field
 - Radiology
 - Long-term Care Facility
 - Racecar Track
 - Operating Room
 - Rodeo Arena
 - Disease Specific Clinic
 - Hockey Rink
 - Ambulance
 - Nuclear Medicine
- A prescriber’s main location of evaluating and treating a patient’s ailment?

“In The Office” and “Similar Settings”

Where’s the storage?

Locked Electronic Accessible Cabinets

Locked and Unlocked Drawers

Safes

Lock Boxes

Refrigerators

Physician’s Medical Bag

Countertops

Locked and Unlocked Cabinets

Dispensing Containers

Cassettes

Vials (traditional)

Vials (PCA)

Syringes

Bags

Tubes or Jars

Capsules

Patches

Narcotics Often Dispensed

- Fentanyl
- Hydromorphone
- Ketamine
- Meperidine
- Methadone
- Morphine
- Sufentanil

Values

- There is a cast of players in a patient's care (pharmacist, physician prescriber, other prescribers, nurse, physical therapist, social worker and patient) that we want to share the same values.
- Unfortunately, that doesn't always happen and diversion occurs.

Diversion Control

Dispense directly to the patient

Versus

Dispensing directly to the prescriber's
"Office"

Dispensing Directly to Patient

Advantages

Pharmacy directly
billing insurance

Disadvantages

Tampering by patient,
family member, or
acquaintance

Improper storage
compromising stability
and sterility

Dispensing Directly to Prescriber's Office

Advantages

Proper Storage for stability
and sterility

Chain of Custody

Decreased chance of
tampering

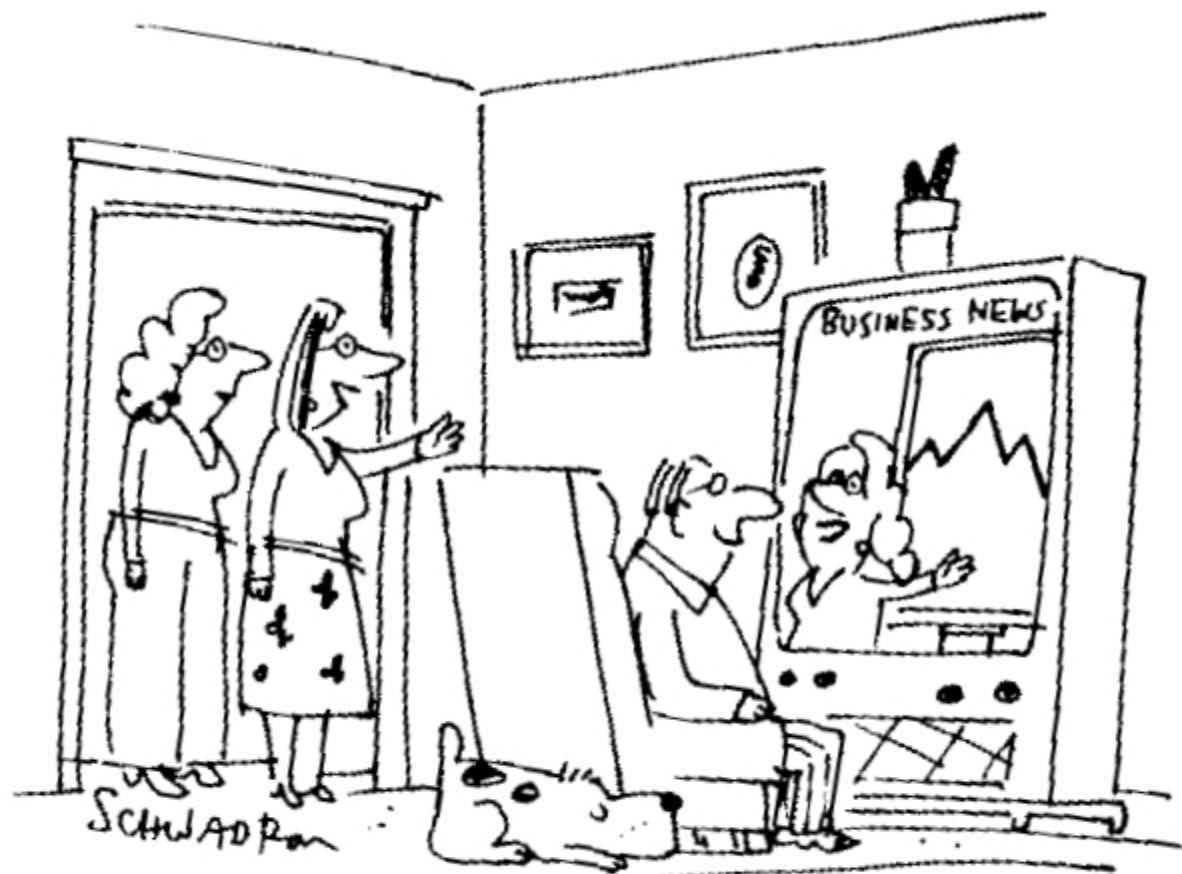
Available for immediate
administration to patient

Disadvantages

An unethical practice

Ultimately...

What is the goal for the patient?



"THANKS TO PAINKILLERS, NED IS NOW ABLE TO WATCH THE ENTIRE MARKET REPORT."

1970 CSA

- The last Controlled Substance Act was written in 1970.....38 years ago.
- Needs to be brought up-to-date to
 - Need to control diversion regarding delivery devices
 - We need to dispose of CSAs differently than 38 years ago
 - Prescribers making house calls for hospice and palliative care
 - More robberies
 - More strengths of manufactured and compounded medications and mixtures of controlled and non-controlled medications available

Manufactured vs Compounded

Why should there be different rules for a prescriber having a manufactured product versus a compounded preparation in their office, in advance of a patient's visit to that office for treatment?

Ideas for state boards of pharmacy and the DEA?

- Update the CSA
- Require Tamper Resistant or Tamper Proof Packaging
- Require dispensing to the prescriber's "office" only
- Define "office"
- Outline recordkeeping requirements for the prescriber's "office"
- Not require manufacture registration
- Documentation requirements for pharmacies and prescribers

Methods of Documentation

- Electronic-locked dispensing cabinets with badge, optical or fingerprint and password access verification
- Locked cabinet with a paper or electronic signature log in and out with limited access.
- DEA 222 use as a pharmacy to prescriber not pharmacy manufacture to prescriber
- SOPs for monitoring handling and storage

Thank You!

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